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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/171,909	05/09/2001	Jayanta Roy-Chowdhury	59046.33 Enz-55(CIP)(PCT)	8638
28171 7590 12/03/2010 ENZO BIOCHEM, INC. 527 MADISON AVENUE (9TH FLOOR) NEW YORK, NY 10022			EXAMINER SCHWADRON, RONALD B	
			ART UNIT 1644	PAPER NUMBER
			MAIL DATE 12/03/2010	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/171,909	<b>Applicant(s)</b> ROY-CHOWDHURY ET AL.	
	<b>Examiner</b> Ron Schwadron, Ph.D.	<b>Art Unit</b> 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-13 is/are pending in the application.
- 4a) Of the above claim(s) 4-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 11-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/15/10 has been entered.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The rejection of claim 1 under 35 U.S.C. 112, first paragraph, as failing to comply with the *written description* requirement for the reasons elaborated in the previous Office Action is withdrawn in view of the amended claims.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claim 1,11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (WO 96/39176) in view of Katz (US Patent 4,950,469) and Harley (US 6,641,813). Applicants arguments have been considered and deemed not persuasive.

Chen et al. teach that oral tolerance to autoantigens can be used to treat antibody mediated autoimmune disease wherein the disease involves antibodies which bind the pertinent autoantigen (see claims 1-13, pages 12-14,40,41). Oral tolerance is a form of "selective immune down regulation" (see specification, page 17, second paragraph). Chen et al. do not teach that the disease provoking antigen is streptococcus which is involved with the pathogenesis of rheumatic fever. Katz et al. teach that rheumatic fever involves an autoimmune antibody response caused by anti streptococcal antibodies which cross react with human tissues (see column 6, first paragraph). Katz teaches that agents which prevent binding of said antibodies could be used to treat rheumatic fever (see column 6, first paragraph). Katz teaches that treatment of rheumatic fever would also include use of antibiotics (see column 6, first complete paragraph). Harley establish that the streptococcus to which Katz refers encompasses *Streptococcus pyogenes* which was known in the art as a species of streptococcus bacteria associated with rheumatic disease (see column 10, first incomplete paragraph). Chen et al. disclose that preparations of whole antigens (aka intact) can be used (see page 18, last paragraph continued on next page). Any preparation administered to humans would not include live pathogenic bacteria (aka the preparation would be inactivated). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Chen et al. teach that oral tolerance to autoantigens can be used to treat antibody mediated autoimmune disease wherein the disease involves antibodies which bind the pertinent autoantigen whilst Katz teaches that teach that rheumatic fever involves an autoimmune antibody response caused by anti streptococcal antibodies which cross react with human tissues wherein the streptococcal antigens would

function as an autoantigen. One of ordinary skill in the art would have been motivated to do the aforementioned because Chen et al. teach use of oral tolerance to prevent antibody responses causing autoimmune diseases and Katz disclose that anti streptococcal antibodies are involved in rheumatic fever and that neutralization of said antibodies could be used to treat said disease.

Regarding applicants comment about Katz, Katz teach that rheumatic fever involves **an autoimmune antibody response caused by anti streptococcal antibodies which cross react with human tissues** (see column 6, first paragraph).

Regarding applicants comments about Chen et al. and the term autoantigen, Chen et al. state in page 8, lines 18-20 of said page that regarding the term autoantigen that *"The term also includes antigenic substances that induce conditions having the characteristics of an autoimmune disease when administered to mammals."*

Regarding applicants comments, the aforementioned sentence indicates that *"The term also includes antigenic substances that induce conditions having the characteristics of an autoimmune disease when administered to mammals."*, indicating that the term autoantigen also includes the aforementioned antigenic substances. Furthermore, as per Katz, cross reactive bacterial antigens which induce autoimmune antibody responses were already known in the art. In addition, Harley confirms the association of Streptococcus pyogenes and rheumatic disease. Regarding applicants comment about Quinn et al. and streptococcus, Katz et al. teach that rheumatic fever involves **an autoimmune antibody response caused by anti streptococcal antibodies which cross react with human tissues**. Harley confirms the association of Streptococcus pyogenes and rheumatic disease. Thus the streptococcal antigen as per disclosed by Katz would **constitute an autoantigen as per the definition of said term in Chen et al.** Regarding applicants comments about Quinn et al. and Gorton et al., Katz et al. teach that rheumatic fever involves **an autoimmune antibody response caused by anti streptococcal antibodies which cross react with human tissues** (see column 6, first complete paragraph). The streptococcal antigen as per disclosed by Katz would **constitute an autoantigen as per the definition of said term in Chen et al.** In KSR Int'l Co. v. Teleflex Inc ., 550 U.S. \_\_\_, 2007 WL 1237837, at \*13 (2007) it was stated that "if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill".

Regarding applicants comments, Chen et al. teach that oral tolerance to autoantigens can be used to treat antibody mediated autoimmune disease wherein the disease involves antibodies which bind the pertinent autoantigen and wherein oral tolerance is a form of “selective immune down regulation” (see specification, page 17, second paragraph). While Chen et al. do not teach that the disease provoking antigen is streptococcus which is involved with the pathogenesis of rheumatic fever, Katz et al. teach that rheumatic fever involves an autoimmune antibody response caused by anti streptococcal antibodies which cross react with human tissues. Chen et al. state in page 8, lines 18-20 of said page that regarding the term autoantigen that “*The term also includes antigenic substances that induce conditions having the characteristics of an autoimmune disease when administered to mammals.*”.

Regarding applicants comments about “artificial antigens” and animal models, Chen et al. disclose the use of antigens in humans that are associated with human autoimmune diseases (see pages 17-18). Chen et al. teach that oral tolerance to autoantigens can be used to treat antibody mediated autoimmune disease wherein the disease involves antibodies which bind the pertinent autoantigen and wherein oral tolerance is a form of “selective immune down regulation” (see specification, page 17, second paragraph). While Chen et al. do not teach that the disease provoking antigen is streptococcus which is involved with the pathogenesis of rheumatic fever, Katz et al. teach that rheumatic fever involves an autoimmune antibody response caused by anti streptococcal antibodies which cross react with human tissues. Chen et al. state in page 8, lines 18-20 of said page that regarding the term autoantigen that “*The term also includes antigenic substances that induce conditions having the characteristics of an autoimmune disease when administered to mammals.*”.

Katz et al. teach that rheumatic fever involves an autoimmune antibody response caused by anti streptococcal antibodies which cross react with human tissues. Thus the streptococcal antigen as per disclosed by Katz would constitute an autoantigen as per the definition of said term in Chen et al. Regarding applicants comments, there is currently no limitation in the claims regarding the dosage of antigen that is used in the claimed method. Chen et al. teach that oral tolerance to autoantigens can be used to treat antibody mediated autoimmune disease wherein the disease involves antibodies which bind the pertinent autoantigen and wherein oral tolerance is a form of “selective immune down regulation” (see specification, page 17, second paragraph). Thus, Chen

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et al. teach a method of “selective immune down regulation”. Applicants arguments involve limitations not recited in the claims under consideration. Regarding applicants comments about “high dose feeding”, the method of Chen et al. is not limited to a method of “high dose feeding”. For example, in claim 1 of Chen et al., the autoantigen is administered at a dosage wherein the autoimmune disease is treated. Thus, the method of Chen et al. does not require “high dose feeding”. In fact, Chen et al., page 16, last paragraph teach:

“As will be understood by those skilled in the art, the dosage will vary with the disease, the antigen administered and may vary with the sex, age, and physical condition of the patient as well as with other concurrent treatments being administered. Consequently, adjustment and refinement on one or both of the dosages used and the administration schedules will be determined based on these factors and especially on the patients response to the treatment. Such determinations, however, require no more than routine experimentation...”. Furthermore, there is no disclosure in the specification of the instant application that any particular dosage of antigen is required to practice the instant invention in humans. The specification, page 12 states:

“This invention provides a process for producing selective immune down regulation in a subject to an infectious bacterial agent. In this process, a reagent or a combination of reagents capable of producing selective immune down regulation and comprising a component or components or fragments thereof of such infectious agent is introduced to the subject, thereby establishing selective immune down regulation in the subject.”.

Thus, the reagent is simply administered at a concentration that results in selective immune down regulation (such as oral tolerance). Regarding the specification, Example 1, said example is not drawn to the claimed method (it does not use a bacterial antigen) and is therefore irrelevant to the invention under consideration. Said example also refers to a specific dosage range wherein said range is not the dosage encompassed by the term “large amounts of antigen” as per Chen et al. It is also noted that none of the claims under consideration recite the administration of any particular concentration of antigen. Regarding applicants comments about Katz, said reference discloses that rheumatic fever involves an autoimmune antibody response caused by anti streptococcal antibodies which cross react with human tissues (see column 6, first paragraph). Katz then discloses that said disease can be treated using an agent that

interferes with said antibodies (see column 6, first paragraph). Thus Katz clearly discloses the role of said antigen in rheumatic fever. In addition, Chen et al. disclose that particular antigens can be identified by screening antigens for binding with antibodies from a patient (see page 18, penultimate paragraph). Chen et al. teach that oral tolerance to autoantigens can be used to treat antibody mediated autoimmune disease wherein the disease involves antibodies which bind the pertinent autoantigen and wherein oral tolerance is a form of "selective immune down regulation" (see specification, page 17, second paragraph). While Chen et al. do not teach that the disease provoking antigen is streptococcus which is involved with the pathogenesis of rheumatic fever, Katz et al. teach that rheumatic fever involves an autoimmune antibody response caused by anti streptococcal antibodies which cross react with human tissues.

6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is (571)272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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